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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,177

01/23/2004

Mark Tengler

NEOS:1007RCE

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11/18/2008

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EXAMINER

ANDERSON, JAMES D

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

11/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/764,177	Applicant(s) TENGLER ET AL.	
	Examiner JAMES D. ANDERSON	Art Unit 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 October 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: 1,6,8,10-12,14-21,25-43 and 45-61.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
 12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
 13. ☐ Other: _____.

/Ardin Marschel/
 Supervisory Patent Examiner, Art Unit 1614

/James D Anderson/
 Examiner, Art Unit 1614

Continuation of 5. Applicant's reply has overcome the following rejection(s): The rejections of claims 9 and 13 are withdrawn in view of Applicant's cancellation of claims 9 and 13.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments have been carefully considered but they remain unpersuasive to overcome the rejections set forth in the previous Office Action. With regard to the 35 U.S.C. 112, first paragraph rejection of claims 1, 6, 8-21, 25-43, and 45-61 (now 1, 6, 8, 10-12, 14-21, 25-43, and 45-61), Applicants allege that the specification sufficiently conveys to a skilled artisan that Applicants were in possession of the present invention. While it is certainly true that Applicants disclose enveloped pharmaceutical compositions comprising a first active for immediate release wherein over 80% of the first active is released within 60 minutes and a second active for extended release wherein over 80% of the second active is released between 90 minutes and 6 hours, the fact remains that such compositions are described in purely functional terms. Applicants are claiming compositions, not methods. As such, Applicants have failed to sufficiently disclose relevant identifying characteristics of the claimed pharmaceutical compositions comprising a first active for immediate release wherein over 80% of the first active is released within 60 minutes and a second active for extended release wherein over 80% of the second active is released between 90 minutes and 6 hours. In other words, Applicants have failed to describe what excipients are present in the claimed compositions and in what amounts so as to give the compositions the release properties claimed. With regard to the 35 U.S.C. 103 rejection of claims 1, 6, 8-21, 25-43, and 45-61 (now 1, 6, 8, 10-12, 14-21, 25-43, and 45-61) as being unpatentable over Devane in view of Dang and Davis, Applicants' arguments have been considered but they are not persuasive for the reasons set forth in the previous Office Action. The Examiner is not persuaded by Applicants' arguments that the combination of references fails to teach or suggest every element of the claims. The cited prior art teaches, suggests, and motivates one skilled in the art to provide pharmaceutical compositions comprising a first agent for immediate release and a second agent for extended release. With respect to the claimed release profiles, to the extent that the cited prior art does not explicitly teach such release profiles, as discussed in the previous Office Action, one skilled in the art is provided with the means and motivation to adjust the extended release coatings of the prior art in order to effect changes in the release profile of the active agents.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614